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## Microbial Risk Assessment: Activities and Applications Within the Food Safety and Inspection Service

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EPA-DHS Conference on Real-World Applications  
and Solutions for Microbial Risk Assessment  
Bethesda, MD

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## FSIS Responsibility

- Public health regulatory agency
  - Farm-to-table food safety system
- Ensure the safety of meat, poultry and processed egg products
  - ~ 7,600 full-time inspectors
  - ~ 5,921 processing establishments inspected daily
  - ~ 1,100 slaughter establishments in which *every* animal inspected
- Statutory requirements
  - FMIA, PPIA, EPIA

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## Foodborne Disease

- Latest CDC estimates indicate the following annual burdens due to foodborne diseases in the U.S. per year:
  - 325,000 serious illnesses resulting in hospitalizations
  - 76 million cases of gastrointestinal illnesses
  - 5,000 deaths

*Campylobacter*  
*Listeria monocytogenes*  
*Salmonella*  
*E. coli* O157:H7

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## Risk Analysis at USDA/FSIS

- Cornerstone of USDA/FSIS food safety program
  - Scientific basis for food safety policies and allocation of inspection resources
  - FSIS corporate strategic plan/SOPs
- Powerful public health tool
  - Allows for transparency and stakeholder involvement to ensure credibility and scientific accountability

Risk Assessors, Risk Managers, Risk Communicators  
Inform Risk Management Options  
Effective Decisions to Improve Food Safety

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## Overview of QMRA Applications

- Inform various agency decisions
  - Industry regulations (standards)
  - Allocation of agency inspection resources
  - Food safety research priorities
  - Equivalence criteria (trade)
  - Recalls
- Scientific basis for food safety decisions
  - Explicitly link policies to public health outcomes

$$p(H|D,I) = p(H|I) \frac{p(D|H,I)}{p(D|I)}$$

Microbial risk assessment integrates a wide variety of science and data to provide a comprehensive understanding of the food safety system.

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## Microbial Risk Assessment Activities: 1998-2003

- USDA/FDA risk assessment for *Salmonella* Enteritidis in eggs and egg products (1998)
- Harvard BSE risk assessment (2001, updated 2003/2005/2006)
- E. coli* O157:H7 in ground beef (2001)
- E. coli* O157:H7 in non-intact beef (2002)
- USDA/FSIS risk assessment for *Listeria* in deli meats (May 2003)
- FDA/FSIS risk ranking of ready-to-eat foods for Lm (2001/updated September 2003)

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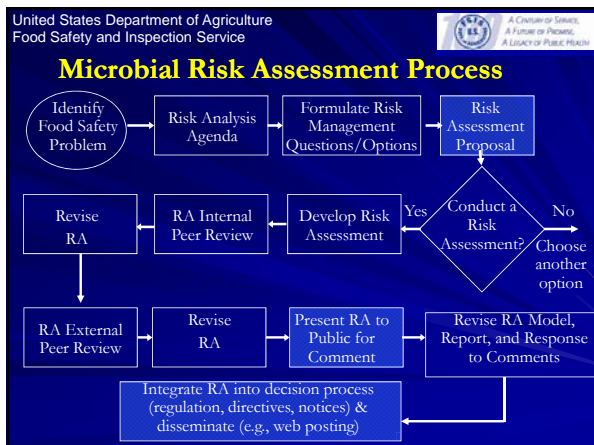
**Microbial Risk Assessment Activities: 2004-2006**

- Risk-based *Listeria monocytogenes* verification sampling algorithm (2005)
- *Salmonella* Enteritidis in shell eggs and *Salmonella* spp. in egg products (2005)
- *Salmonella* spp. in ready-to-eat meat and poultry products (2005)
- *C. perfringens* in ready-to-eat meat and poultry products (2005)
- USDA/FSIS risk assessment for *Salmonella* in beef and poultry (2006)
- Poultry Slaughter Risk Assessment (draft 2006, updated 2008)

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**Microbial Risk Assessment Activities: 2007-2008**

- Risk-based *E. coli* O157:H7 verification sampling algorithm (2007)
- Comparative risk assessment for *L. monocytogenes* in ready-to-eat meat and poultry products (draft 2004/updated 2008)
- FoodNet Interagency Salmonella Attribution Model (2008)
- Risk Assessment to Guide Performance Standards for Salmonella and Campylobacter in Poultry (2008)
- Pre-harvest Intervention *E. coli* risk assessment (draft 2008)
- Interagency Highly Pathogenic Avian Influenza (2008)



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**Application: *Listeria* Risk Assessments**

- FDA-FSIS Quantitative Risk Assessment for *Listeria monocytogenes* in Ready-to-Eat Foods
- FSIS *Listeria* Risk Assessment
- Risk-based *Listeria monocytogenes* Verification

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**Public Health Context: *Listeria monocytogenes* (Lm)**

- Causes septicemia, abortion and encephalitis in humans and in animals
- Incubation period 7 - 60 days
- Human listeriosis occurs in both epidemic and sporadic cases
- Affects predominantly elderly and immuno-compromised people, pregnant women and newborns
- Approx. 2,500 human cases/year in the U.S., resulting in 350 - 450 deaths/year
- Responsible for majority of microbial food recalls
- National health objective is to decrease incidence of listeriosis by 50% to 0.25 per 100,000 persons



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**General Risk Management Questions**

- Which ready-to-eat foods pose the greatest risk of listeriosis?
  - 2003 FDA-FSIS Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat (RTE) Foods
- Which interventions effectively control Lm?
  - 2003 FSIS Risk Assessment for *Listeria monocytogenes* in Deli Meat
- How can FSIS target its inspection resources to effectively address Lm?
  - 2005 FSIS Risk-based Verification Sampling for Lm in ready-to-eat meat and poultry products

## Which Ready-to-Eat Foods Pose the Greatest Risk of Listeriosis?

- Risk Assessment: 2003 FDA/FSIS *Listeria* Risk Assessment
- Estimated the relative risks of serious illness and death associated with consumption of different types of RTE foods
- Estimates exposure among three age-based categories and the total U.S. population; used a single dose-response relationship
- Probabilistic retail-to-table exposure assessments



## Diagram of 2003 FDA/FSIS *Listeria* Risk Assessment Model (example: frankfurters)

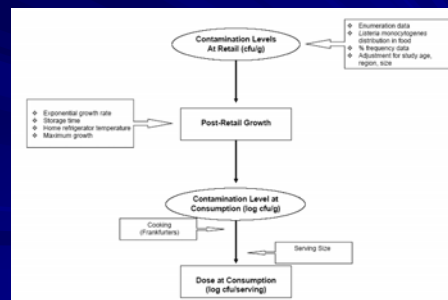


Figure 3B-1. Components of the Exposure Assessment Model

## Relative Risk Ranking and Predicted Median Cases of Listeriosis for U.S. Population on per Serving and per Annum Basis

Relative Risk Ranking		Predicted Median Cases of Listeriosis for 23 Food Categories			
		Per Serving Basis <sup>a</sup>		Per Annum Basis <sup>b</sup>	
		Food	Cases	Food	Cases
1	High Risk	Deli Meats	7.7x10 <sup>-8</sup>	Deli Meats	1598.7
2		Frankfurters, not reheated	6.5x10 <sup>-8</sup>	Pasteurized Fluid Milk	90.8
3		Pâté and Meat Spreads	3.2x10 <sup>-8</sup>	High Fat and Other Dairy Products	56.4
4		Unpasteurized Fluid Milk	7.1x10 <sup>-9</sup>	Frankfurters, not reheated	30.5
5		Smoked Seafood	6.2x10 <sup>-9</sup>	Soft Unripened Cheese	7.7
6		Cooked Ready-to-Eat Crustaceans	5.1x10 <sup>-9</sup>	Pâté and Meat Spreads	3.8
7	Moderate Risk	High Fat and Other Dairy Products	2.7x10 <sup>-9</sup>	Unpasteurized Fluid Milk	3.1
8		Soft Unripened Cheese	1.8x10 <sup>-9</sup>	Cooked Ready-to-Eat Crustaceans	2.8
9		Pasteurized Fluid Milk	1.0x10 <sup>-9</sup>	Smoked Seafood	1.3

\* Only the top 9 riskiest food categories are shown

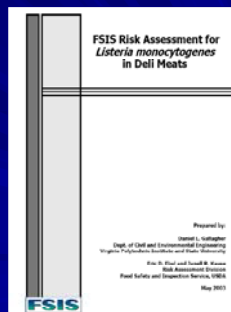
## Risk Characterization

- High risk per serving
  - Deli Meats
  - Frankfurters, not reheated
  - Pâté and Meat Spreads
  - Unpasteurized Fluid Milk
  - Smoked Seafood
  - Cooked Ready-to-Eat Crustaceans
- High risk per year (cases)
  - Deli Meats (1598.7)
  - Pasteurized Fluid Milk (90.8)
  - High Fat and Other Dairy Products (56.4)
  - Frankfurters, not reheated (30.5)



## Which Interventions Effectively Control Lm?

- 2003 FSIS *Listeria* Risk Assessment
- Evaluated the effectiveness of industry controls in mitigating the risk of listeriosis associated with deli meats industry regulations (standards)
  - Post-lethality intervention
  - Growth inhibitors
  - Sanitation
- Built from FDA/FSIS *Listeria* risk assessment
- Processor-to-table risk assessment

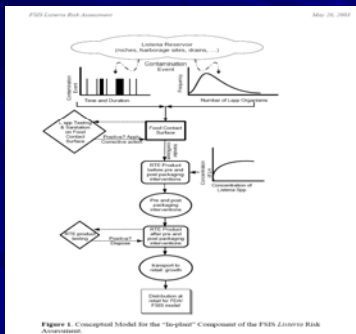


## Specific Risk Management Questions

- What is the effectiveness of testing and sanitation of food contact surfaces on mitigating product contamination and reducing the subsequent risk of illness?
- How effective are other pre- and post-packaging interventions in mitigating product contamination and reducing the subsequent risk of illness?
- What guidance can be provided on testing and sanitation of food contact surfaces for *Listeria* species?



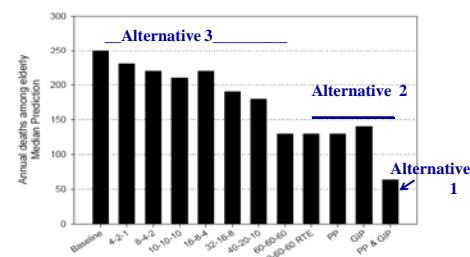
## Diagram of the 2003 FSIS *Listeria* Risk Assessment Model



**Figure 1.** Conceptual Model for the "In-place" Component of the FSNIS Littering Risk Assessment.

## 2003 FSIS *Listeria* Risk Assessment Output

Figure 21 depicts estimated numbers of deaths among the elderly for the scenarios tested. For the proposed minimal amount of food contact surface testing (i.e., the 4-2-1 scenario: FSIS, 66 FR 12589, February 27, 2001), the estimated median number of deaths among the elderly is reduced by about 20 per year.



## USDA/FSIS Risk Management Strategy

**Interim Final Rule (issued June 2003, effective October 6, 2003; 9 CFR 430 RTE)**

- Based on the 2003 FSIS *Listeria* risk assessment and the 2003 FDA-FSIS Risk-Ranking for Lm in ready-to-eat foods
- Established three alternative control measures
  - Post-lethality treatment and antimicrobial agent/process with sanitation (Alt. 1)
  - Post-lethality treatment (Alternative 2a) or antimicrobial agent/process with sanitation (Alt. 2b)
  - Sanitation alone (Alt. 3)

**FSIS Directive 10,240.4 (10/2/03)**

- Established a risk-based sampling program to verify compliance with Lm Rule

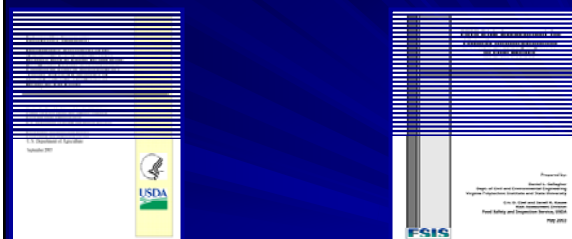
## How Can FSIS Allocate Its Sampling Resources According to Risk?

## FSIS Risk Assessment for Risk-Based Verification Sampling of *Listeria monocytogenes*

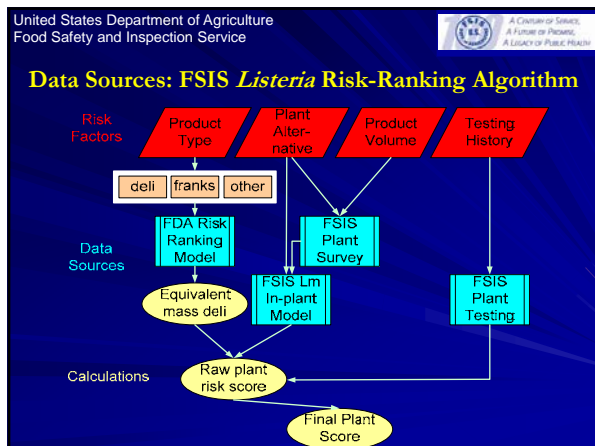


## Purpose of the FSIS Risk-Based *Listeria* Verification Program

- To prevent adulteration of product by Lm.
- To focus USDA/FSIS verification sampling efforts on establishments producing product predicted to pose the greatest risk of listeriosis based on two previously developed *Listeria* risk assessments and real time laboratory data.
- To evaluate an establishment's food safety system so that FSIS can focus on establishments with less effective Lm control measures.
- To provide an appropriate incentive for establishments to adopt more effective Lm control measures.
- To protect public health.



Risk-based verification algorithm is directly informed by previous risk assessments.



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***Listeria monocytogenes* Risk-Based Verification**

FSIS implemented a risk-based verification testing program in January 2005


- Previously, establishments were tested randomly; now, using the risk ranking algorithm, frequency of sampling is dependent on relative risk for Lm contamination
  - Approximately 10,000 product samples annually
  - Expanded to collect product, environmental and food contact samples in April 2006
  - Risk is defined quantitatively for each facility

Enhances FSIS' focus on verification and provides increased confidence in public health protection.

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**Lessons Learned**


- Must have well defined risk management questions
- QMRAs are not a "one size fits all"
- Complexity of the MRA depends on the purpose for developing the risk assessment
- Risk assessors and risk managers are independent, but interdependent
- Iterative interaction between risk assessors and risk managers is needed to develop QMRAs useful to informing policies



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**Lessons Learned**

- MRA models can be modular and built more quickly using prior risk assessment models
- Integrating economics and risk assessment into a single model saves time in decision-making
- Move beyond simply building a risk assessment and use as a predictive tools - conduct scenario analyses
- Characterization of certainty of risk estimates provides critical information to decision makers (sensitivity analysis/2<sup>nd</sup> order modeling)
- Rigorous peer review is essential to ensuring intended utility



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**Future Directions**

- USDA/FSIS is committed to developing MRAs
  - High level of transparency in the decision-making process
  - Readily share information to facilitate more expedient development and application of MRA (post models on the web)
  - Web accessible and downloadable models
  - Develop and publish standard modeling methods
  - Investment into agency IT infrastructure and data integration to support quantitative MRAs
  - Integrate MRA process models into IT systems and update on an annual basis
- FSIS will continue to expand the integration and application of QMRA to inform food safety decisions designed to improve public health through safer food

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**Thank You**

**Website:**

[www.fsis.usda.gov/Science/Risk\\_Assessments/index.asp](http://www.fsis.usda.gov/Science/Risk_Assessments/index.asp)